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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Asgeir Saebo *et al.*
Serial No.: 09/544,084
Filed: 04/06/2000
Entitled: Conjugated Linoleic Acid Compositions

Group No.: 1617
Examiner: Wang, S.

**TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION - 37 CFR § 192)**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

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Dated: February 24, 2006

By: 

Mary Ellen Waite

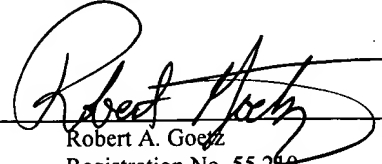
Sir or Madam:

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal mailed on November 24, 2004 and received in the Mail Room on November 29, 2004 and the Order Returning Undocketed Appeal to Examiner mailed January 31, 2006 from the Board of Patent Appeals and Interferences, for Applicant to file a substitute Appeal Brief in compliance with 37 CFR § 41.37.
2. STATUS OF APPLICANT
This application is on behalf of
other than a small entity.
3. FEE FOR FILING APPEAL BRIEF
Pursuant to 37 CFR § 1.17(g), the fee for filing the Appeal Brief is:
Fee for Filing Appeal Brief \$500.00
4. EXTENSION OF TERM
The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply.
No extension is due at this time.
5. TOTAL FEE DUE
No fee is due at this time.
6. FEE PAYMENT
No fee is due at this time.
Applicants paid the required \$500.00 filing fee for an Appeal Brief and the \$120.00 one month extension of time with the Appeal Brief filed on March 2, 2005.

7. **FEE DEFICIENCY**

If any additional fee is required, charge Account No. 08-1290.

Dated: February 24, 2006


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Sæbo *et al.*

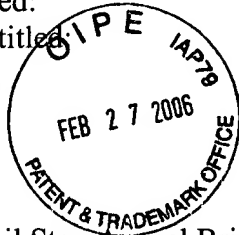
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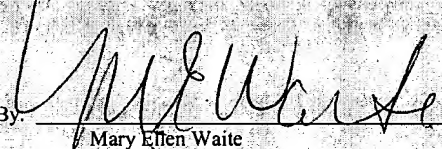
Entitled: **CONJUGATED LINOLEIC ACID COMPOSITIONS**



APPELLANTS' BRIEF

APPEAL NO.:

Mail Stop Appeal Brief - Patents
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P.O. Box 1450
Alexandria, VA 22313-1450

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Dated: <u>February 24, 2006</u>	By:  Mary Ellen Waite

Sir or Madam:

This Brief is in furtherance of the Notice of Appeal filed November 29, 2004.

The fees required under § 1.17(h) and any required Petition for Extension of Time for filing this Brief and fees therefore are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This Brief is transmitted in triplicate. [37 C.F.R. § 41.37(c)].

This Brief contains these items under the following headings and in the order set forth below [37 C.F.R. § 41.37(c)]:

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I. REAL PARTY IN INTEREST

The real party in interest is Natural ASA, a Norwegian Corporation.

II. RELATED APPEALS AND INTERFERENCES

A Decision On Appeal was mailed July 20, 2005, for Appeal No. 2005-0150 relating to U.S. Patent Application Serial No. 09/271,024, filed March 17, 1999. A copy of this Decision is provided in Section X. A Decision On Appeal was mailed August 30, 2005, for Appeal No. 2005-1578 relating to U.S. Patent Application Serial No. 09/132,593, filed August 11, 1998. A copy of this Decision is provided in Section X. A Notice Of Appeal was filed on July 6, 2004, for U.S. Patent Application Serial No. 09/949,458, filed September 7, 2001. There are no other related appeals or interferences known to Appellants, Appellants' legal representative, or the Assignee.

III. STATUS OF CLAIMS

Claims 1 - 30 were filed in the original application. During prosecution of the application, Claims 19-30 were canceled. Claims 1-18 and 31 have been rejected by the Office in the Final Office Action dated August 25, 2004. Therefore, Claims 1-18 and 31 are pending in this appeal. No other claims are pending. Thus, Appellants appeal the Final Office Action of August 25, 2004. The Claims, as they now stand, are set forth in the Claims Appendix.

IV. STATUS OF AMENDMENTS

Appellants' Response to the Office Action filed on May 7, 2004, has been entered per the Office Action dated August 25, 2004. Amendments to the claims that were made in the May 7, 2004 Response were acknowledged in the Final Office Action dated August 25, 2004. Thus, there are no pending amendments not entered into the record.

V. SUMMARY OF CLAIMED SUBJECT MATTER

This invention relates to the field of nutrition and the supplementation of feedstuffs and food with alkyl esters of conjugated linoleic acid. In particular, methods for producing food products comprising conjugated linoleic acid esters are provided. A method for producing a food product containing conjugated linoleic acid esters comprising providing linoleic acid esters, an alcoholate catalyst, and a foodstuff; treating the linoleic acid esters with the alcoholate catalyst to provide conjugated linoleic acid esters; and combining the foodstuff with the conjugated linoleic acid esters to produce a food product is described, for example, in Example 10. Linoleic acid esters derived from oils selected from the group consisting of safflower, sunflower, and corn oil are described, for example, in Examples 1, 2, 3, 4, 7, 8, 9, and 17, and within the Specification at pages 12 and 18-19. Alcoholate catalysts selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate are described, for example, in Examples 17 and 18, and in the Specification at pages 8, and 18-19. Treating conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant, and combining the antioxidant with the conjugated linoleic acid esters and the foodstuff to produce a food product is described, for example, in Examples 16, 17 and 18, and in the Specification at pages 22-24. An antioxidant selected from the group consisting of α -tocopherol,

β -tocopherol, lecithin, ascorbylpalmitate, and BHT is described, for example, in Example 15, and in the Specification at pages 5, 21, and 23-24. Treating conjugated linoleic acid esters under conditions such that the volatile organic compound content of the conjugated linoleic acid esters is less than 5 ppm after storage is described, for example, in Examples 12, 13, and 16, and in the Specification at pages 21-25.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are two grounds of rejection to be reviewed on appeal:

Issue 1 – Whether Claims 1-18 and 31 are obvious under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 (hereinafter, “the Sæbo patent”) in view of U.S. Patent No. 5,760,082 (hereinafter, “the Cook patent”); and

Issue 2 – Whether Claims 1-18 and 31 are obvious over the Cook patent in view of WO97/18320 (hereinafter, “the Cain patent”) and U.S. 3,162,658 (hereinafter, “the Baltes patent”) in further view of U.S. 5,885,594 (hereinafter, “the Nilsen patent”).

VII. ARGUMENT

A. Issue 1 - Claims 1-18 and 31 Are Not Obvious Under The Judicially Created Doctrine Of Obviousness-Type Double Patenting.

Claims 1-18 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of the Sæbo patent in view of the Cook patent. The Examiner asserts that the Sæbo patent claims a food product containing conjugated linoleic acid, and that

the Cook patent teaches that the derivative of conjugated linoleic acid, including esters, are similarly useful as the free acid in food products (1st Office Action, page 3).

However, the doctrine of obviousness-type double patenting requires that there be a common relationship of **inventorship** and/or **ownership** of two or more patents or applications (see MPEP §804). Moreover, since the doctrine seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis is necessarily on the **claims** in the multiple patents or patent applications involved in the analysis (see MPEP §804). Since the Cook patent does not have either inventorship or ownership in common with the present application, this doctrine cannot apply. Moreover, the Examiner combined the **disclosure** in the Cook patent with the **claims** of the Sæbo patent, which is an incorrect analysis under the doctrine. Therefore, the Applicants the rejection of the claims on this basis should be withdrawn.

B. Issue 2 - Claims 1-18 And 31 Are Not Obvious Over The Combination Of The Cook, Baltes And Nilsen Patents.

Claims 1-18 and 31 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over the combination of the Cook, Baltes, and Nilsen patents. A *prima facie* case of obviousness requires the Office to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without

more, entitles the Applicants to allowance of the claims at issue.¹ The Office has failed to establish a *prima facie* case of obviousness because 1) the Office has not provided a motivation to combine the references; 2) the Office is applying hindsight reconstruction; 3) the Office is improperly disregarding the Sæbo Declaration; and 4) the Office is misapplying the law.

1. The Office Has Ignored Evidence Presented By The Applicants That Establishes That Patentable Weight Should Be Given To The Combination Of Adding Alcoholate Catalyzed CLA To Food Products.

Applicants **have provided evidence** as to why a method that uses CLA produced by alcoholate catalysis to make food products is non-obvious. The Office, however, has ignored the evidence presented by the Applicants establishing that patentable weight should be given to the combination of adding alcoholate catalyzed CLA to food products. In particular, in reference to the patentability of the claims, the Office stated:

[R]egarding the limitation about the method to obtain the conjugated linoleic acid, note a method of making ingredients is not seen to render patentable weight to a method which employs such ingredients, absent evidence to the contrary." Office Action dated July 16, 2003; Paper Number 20030716; page 4.

Applicants first note that this statement ignores the actual language of the claims, which specify the particular step of using an alcoholate catalyst. This is contrary to the Office's statement that the claims only employ such ingredients. Applicants fail to see how the Office can simply ignore a process step and reason that a specific step cannot provide patentable weight to a method claim. The Office provided no legal authority on this point. Applicants are not aware of any such legal precedent.

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

Furthermore, Applicants **have provided** evidence that it is not obvious to simply use a process that was previously used for the production of CLA for industrial uses with a method for food production. This evidence is provided by the Declaration of Asgeir Sæbo (provided in the Evidence Appendix). As detailed in the Sæbo Declaration, none of the references teach or suggest using CLA isomerized with alcoholate catalysts in food products. Furthermore, as explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption. Thus, the Office's attempt to claim that the compositions of Baltes could be used in a food product is misguided.

In fact, the Baltes reference indicates that the uses the products are suited for are industrial in nature. In particular, Baltes et al. describe methods for producing conjugated linoleic acids described as being "valuable industrial products" for use in formation of "light colored polymers," for use as "ingredients of lacquers or coating compositions" or as "ingredients of plasticizers" and as "reaction components in the preparation of resins" (Baltes et al., *col. 9, ll. 47-60*). As such, the Baltes reference is directed to the production of substitutes for tung oil that are not suitable for consumption. The tung oil substitutes described in Baltes et al., are intended for industrial uses such as for drying oils, varnishes, and lacquers. Consequently, Baltes et al., describes methods for producing toxic oil substitutes for non toxic oils (tung oil). Nothing in the Baltes et al. reference teaches or suggest the desirability--or even applicability--of using the methods disclosed therein to produce food products.

Thus, Applicants **have provided evidence** as to why a method that uses CLA produced by alcoholate catalysis to make food products is non-obvious. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.²

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.³

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.⁴

Accordingly, even if the Office had established a *prima facie* of obviousness in a preceding office action (and Applicants contend that he did not), the Examiner must respond to Applicants

² MPEP §§2144.08; emphasis added).

³ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

⁴ *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

arguments. The failure to rebut either the arguments or the evidence advanced by the Applicants is reversible error under *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996):

In *In re Alton*, the applicants submitted a declaration in order to rebut a *prima facie* case of inadequate written description by the Board of Appeals in an earlier appeal. *Id.* at 1173. Instead of addressing the arguments presented in the declaration, the Examiner dismissed the declaration as opinion evidence that was entitled to little weight. *Id.* at 1173-745. The Federal Circuit remanded the case to the Board, holding that the Board committed error in both viewing the declaration as opinion evidence and dismissing the declaration "without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case" of unpatentability. *Id.* at 1174. These bases for reversal were independent. With respect failure to provide an adequate explanation of why the declaration failed to rebut the *prima facie* case, the Federal Circuit found that:

In sum, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

Id. at 1176. In particular, the Federal Circuit held that the examiner failed to address specific points made in the declaration concerning modifications of the amino acids sequence of protein. *Id.*

In re Alton is directly applicable to the present facts. Instead of addressing the arguments presented in the Sæbo Declaration, the Office has provided only conclusory statements and failed to address the particular evidence offered in the Declaration. In particular, the Sæbo Declaration provides evidence that:

- "The Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and

conjugated linolenic acid (CLnA) for technical purposes such as drying oils and paint varnishes.

- The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in many ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manners."
- Based on the disclosure of the Baltes, Cook and Lievense patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.
- Other disclosure in the Baltes patent also indicates the unsuitability of the methods for the production of edible CLA.
- The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunsaturated fatty acids. These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts of breakdown products and unwanted polymers, especially when conjugated.
- However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

The only rebuttal of this evidence is provided in the Office Action dated December 28,

2001. The Examiner's attempted rebuttal, in its entirety, is as follows:

The declaration filed October 18, 2001 [the Sæbo Declaration] is insufficient to overcome the rejection of claims 1-30 set forth above because: the teaching of Baltes et al. is not limited to the particular oil disclosed in the examples therein. Baltes teaches a general method for isomerising unconjugated polyethenoid to conjugated polyethenoid. See, column 1, lines 13-16. The starting material may be any unconjugated polyethenoid compounds or products containing them. See column 8, lines 20-68. Further, applicant appears to argue the employment of the reaction mixture to foodstuff, what is actually in the claims are the compounds, i.e., conjugated linoleic esters. ("to provide conjugated linoleic acid esters", see the claims in the instant application). Office Action dated December 21, 2001; Paper Number 12; page 5.

This response completely fails to respond to any of the points listed above. The Office states that Baltes is not limited to any particular oil. However, this fails to respond to the conclusion advanced by Mr. Sæbo that one skilled in the art would read the application to be directed to oils with high levels of triunsaturated fatty acids because a substitute for Tung oil was being sought. The Office further states that Baltes teaches the use of the resulting polyethenoid compounds for "any" product. However, this statement ignores the evidence advanced that a person of ordinary skill in the art would read Baltes as being directed to use of CLA for technical purposes, such as in paints in varnishes. Finally, the Office, states that "applicant appears to argue the employment of the reaction mixture to foodstuff" and dismisses the argument the claims are allegedly (and mistakenly) to compounds. This is precisely the point and indeed, what is claimed! **The use of the method of Baltes to produce CLA for use in foodstuffs is not obvious. As discussed above, the Examiner has failed to examine the invention as a whole.**

As a result, Applicants respectfully request that the Examiner reconsider the evidence offered in the Sæbo Declaration. This evidence establishes that cited references cannot be properly combined and thus rebuts a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the claims be passed to allowance.

2. There Is No Motivation To Combine The References In The Manner Indicated By The Office

The Office fails to provide suitable evidence of a motivation to combine the Cook, Baltes, and Nilsen patents, thus a *prima facie* case of obviousness has not been established. The Office has made the following statements:

The "well-known" conclusion is supported by the teaching of Baltes et al. Cain et al. The instant claims are drawn to a method of making CLA and using CLA in food product. If the method of making CLA herein claimed is well-known, and using CLA in food product is well-known, the claimed

method would have been obvious. Office Action dated February 11, 2004; Paper Number 20040206Feb2004 OA pages 5-6.

In the instant situation, the prior art teaches the employment of CLA as food ingredient was known, and using alcoholic catalyst for making CLA was also known, the employment of CLA made by alcoholic catalyst for food would have been obvious to one of ordinary skill in the art. *There is no need of invoking high level of skill in the art.* Office Action dated August 25, 2004; Paper Number 20040819; pages 5; emphasis added.

Applicants respectfully submit that these statements are **misapplications of the law**.

The Office's basic argument is that **if** two things are well known (alcoholate catalysis and CLA in food), **then** the combination of the two things is well known (using CLA produced by alcoholate catalysis in food). Indeed, the Office goes so far as to state that in such circumstances, "[t]here is no need of invoking high level of skill in the art." This reasoning is completely devoid of any motivation to combine. Indeed, the only reasoning provided is that the two things are "well known."

The Federal Circuit has expressly forbidden this approach:

The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. **Instead, the Board merely invoked the high level of skill in the art.** If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness (Emphasis added).

In re Rouffet, 47 USPQ2d 1453 (Fed. Cir. 1998). In the instant application, the sole basis for combination is the allegedly "well-known" status of two separate concepts. The Examiner's combination on this basis is inadequate as a matter of law.

The Office has also failed to analyze the invention as a whole. When analyzed as a whole, the use of a method for making CLA is non-obvious when the CLA is going to be utilized for food. "That each element in a claimed invention is old or unpatentable does not determine the nonobviousness of the claimed invention as a whole." *Custom Accessories v. Jeffrey-Allan Industries Inc.*, 807 F.2d 955, 1 USPQ 2d 1196, 1198 (Fed. Cir. 1986); See also *Brantingson Fishing Equipment Co. v. Shimano American Corp.*, 9 USPQ 2d 1669, 1672 (Fed. Cir. 1988). Put another way: "Only God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 225 USPQ 26, 31 n. 3 (Fed. Cir. 1985) (quoting from Markey, "Why Not the Statute," 65 JPOS 331, 333-334 (1983)).

The *Fromson* case is particularly relevant here. In that case, the inventor developed a process for photolithography using 1) aluminum as a substrate, 2) oxide coatings by anodization, 3) silication, and 4) application of light-sensitive resins. The district court correctly found that each of these elements individually were known in the art - but incorrectly concluded, on the basis of the unpatentability of each element, that the combination of these steps was unpatentable. On appeal, the Federal Circuit pointed to the "fundamental error" of the district court, noting: "At no point did the court indicate, nor does the record indicate, a basis on which it can be said that the making of that combination would have been obvious when it was made." *Fromson, supra* at 31.

Likewise, in the instant case there has been showing of why one would be motivated to use the alcoholate catalysis process in the production of CLA for food uses as claimed. Absent a motivation to combine the references, the Office has not established a prima facie case of obviousness.

The Office contended that the *Custom Accessories, Brantingson Fishing Equipment Co.*, and *Fromson* cases are not relevant to the instant invention. In particular, the Office stated:

[T]he cited cases, *Fromson* in particular, are not suitable for the instant situation. Particularly, In *Fromson*, each and every steps and the materials involved are closely related in terms of time and space, each step would affect the others. It would be impossible to separate the step and materials involved. In the instant situation, the two ingredients involved, CLA and food could be made separately in term of space and time. Method of making one ingredients would not affect the other. Office Action dated August 25, 2004; Paper Number 20040819; pages 6.

The Applicants contend that the Examiner is misunderstanding the holding of the *Fromson* case. In particular, the *Fromson* case holds that the unpatentability of a set of elements does not render the combination of the references obvious. As noted, in the instant case, there has been showing of why one would be motivated to use the alcoholate catalysis process in the production of CLA for food uses as claimed. As such, the *Fromson* case is particularly relevant because the Office is attempting to do precisely what the *Fromson* court deemed unacceptable. Accordingly, the Office has not established a prima facie case of obviousness and that the claims should be passed to allowance.

The Office further contended:

As to Baltes' teaching, the examiner restates that Baltes reference does not expressly limited to produce CLA for coating. Note question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must be considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. Contrary to applicants' assertion, Baltes state "The invention relates to a process for substantially complete catalytic conversion of compounds of unconjugated polyethenoid acid into compounds of conjugated enthenoid acid." (column 1, lines 13-16). "It will be appreciated from the above that this invention is not limited to the materials, steps, conditions and other details specifically described above and can be carried out with various modification. Thus, it will be understood that the process of this invention is broadly applicable to any unconjugated polyehtenoid acid compounds and products containing

them.” (column 8, lines 20-50, examiner emphasis added). Baltes particularly claims the process for the catalytic isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers using alkali metal monohydric alcoholate (see, particularly, claim 10-12). Office Action dated August 25, 2004; Paper Number 20040819; pages 4-6-7.

The Office takes this statement completely out of context. As pointed out in the Declaration of Asgeir Sæbo (discussed in more detail below), Baltes teaches the use of alcoholate catalysts to produce CLA for use in industrial products such as paints and varnishes. **Baltes fails to address the use of CLA made by these methods in food products.** Thus, a person of ordinary skill in the art reading Baltes would interpret the statement quoted by the Office as teaching that the processes of Baltes could be used to produce CLA for use in industrial type products, not food products. As such, this so-called "suggestion" from Baltes cannot serve as motivation to combine the references.

3. The Office's Reasoning Demonstrates Hindsight Reconstruction

The Office has applied hindsight reconstruction to combine the Cook, Baltes, and Nilsen patents. As noted in the *In re Rouffet* case cited above, hindsight reconstruction is not permitted. The Office, however, relies upon *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) for the proposition that:

[I]t must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

To the extent that this 1971 C.C.P.A. case appears to condone hindsight reconstruction when providing a motivation to combine references, the Federal Circuit has *sub silentio* overruled this proposition, and has emphatically stated that hindsight reconstruction is not proper (as detailed below).

The Federal Circuit has repeatedly warned against using hindsight reconstruction as a test of obviousness. A few examples of such cases include: *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention"); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720 (Fed. Cir. 1990) (The inappropriateness of hindsight as a test of obviousness was, in point of fact, discovered, and articulated lucidly, over three centuries ago, by Milton, who, in *Paradise Lost* Part IV, L. 478-501, stated "The invention all admired, and each how he To be the inventor missed; so easy it seemed, Once found, which yet unfound would have thought, Impossible!"); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068 (Fed. Cir. 1993) ("The motivation to combine references can not come from the invention itself"); *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566 (Fed. Cir. 1996) ("To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction-an illogical and inappropriate process by which to determine patentability"); *W.L. Gore & Assocs., Inc. v. Garlock Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with the knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher ..."). Accordingly, to the extent the

Office has admitted reliance on hindsight reconstruction, that reliance is misplaced as a matter of law.

4. The Examiner's Citation Of *In re Boesch* Is Inappropriate

The Examiner has cited *In re Boesch*, 205 USPQ 215 (CCPA 1980) for the proposition that:

Further, purifying CLA composition by using silica gel (adsorbent) is seen to be obvious since silica gel is well known for purification and separation purpose. Having a limitation of the volatile organic compound (VOC) in food product (whether it the limitation after storage or before storage) is considered an optimization of a result effective parameter, which is considered within the skill of the artisan. Office Action dated August 25, 2004; Paper Number 20040819; pages 4-5.

The Examiner is respectfully directed to the MPEP at §2144.05 which states a "particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimization of workable ranges of said variable might be characterized as routine experimentation." The MPEP additionally cites *In re Antonie*, 559 F.2d 618 (CCPA 1997) for the proposition that the failure of the prior art to recognize a result-effective variable results in the nonobviousness of a claimed range. This is contrasted with *In re Boesch*, in which the court held that the prior art suggested proportional balancing to achieve desired results in the formation of an alloy.

In the instant case, the amount of VOC is not a result effective variable, it is a property which results from the proper treatment and handling of the CLA. It is noted, however, the underlying methods of treatment may involve result effective parameters, for example, silica adsorption with particular amounts of silica for the removal of metal ion contaminants. The claims are not limited to the methods and thus the result-effective variable analysis is inactive.

Applicants further note that this treatment step is not recognized by the prior art as a treatment method for CLA products and thus, if it were claimed, would actually establish the patentability of the claims.

VIII. CLAIMS APPENDIX

1. (previously amended) A method for producing a food product containing conjugated linoleic acid esters comprising:
 - a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters; and
 - c) combining said foodstuff with said conjugated linoleic acid esters from step (b) to produce a food product.
2. (original) The method of Claim 1, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
3. (previously amended) The method of Claim 1, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.
4. (previously amended) The method of Claim 1, wherein step (c) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (d) to produce said food product.
5. (previously amended) The method of Claim 4, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.
6. (previously amended) The food product produced according to the method of Claim 1, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.
7. (previously amended) A method for producing a food product containing conjugated linoleic acid comprising:
 - a) providing:

- i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
 - c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid;
and
 - d) combining said foodstuff with said conjugated linoleic acid from step (c) to produce a food product.
8. (original) The method of Claim 7, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
9. (previously amended) The method of Claim 7, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.
10. (previously amended) The method of Claim 7, wherein step (d) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.
11. (previously amended) The method of Claim 10, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.
12. (previously amended) The food product produced according to the method of Claim 7, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.
13. (previously amended) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:
- a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst, and
 - iii) a foodstuff; and

- b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
- c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and
- d) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties from step (c) to produce a food product.

14. (original) The method of Claim 13, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

15. (previously amended) The method of Claim 13, wherein said alcoholate catalyst is selected from the group consisting of sodium methyllate, potassium methyllate, sodium ethyllate, and potassium ethyllate.

16. (previously amended) The method of Claim 13, wherein step (d) further comprises treating said triglycerides containing conjugated linoleic acid moieties with an adsorbing agent, providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.

17. (previously amended) The method of Claim 16, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.

18. (previously amended) The food product produced according to the method of Claim 13, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

19-30. (canceled)

31. (previously presented) A method for producing a food product containing conjugated linoleic acid esters comprising:

- a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;

- b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
- c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm after storage;
- d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

IX. EVIDENCE APPENDIX

Per 37 C.F.R. §41.37(c)(ix), a copy of October 12, 2001, Declaration of Asgeir Saebo is provided with the present appeal brief.

X. RELATED PROCEEDINGS APPENDIX

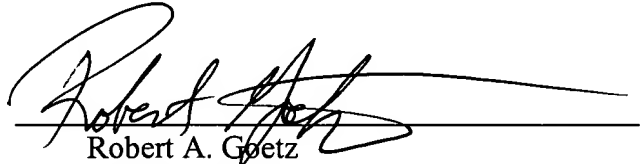
A copy of the Decision On Appeal mailed July 20, 2005, for Appeal No. 2005-0150 for U.S. Patent Application Serial Nos. 09/271,024, filed March 17, 1999, is provided with the present appeal brief.

A copy of the Decision On Appeal mailed August 30, 2005, for Appeal No. 2005-1578 for U.S. Patent Application Serial Nos. 09/132,593, filed August 11, 1998, is provided with the present appeal brief.

XI. CONCLUSION

For the foregoing reasons, it is submitted that the Office's rejection of Claims 1-18 and 31 was erroneous, and reversal of the rejection is respectfully requested. Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Office.

Dated: February 24, 2006


Robert A. Goetz
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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

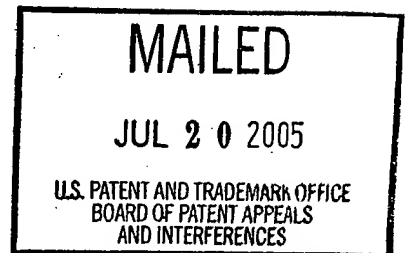


BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ASGEIR SAEBO, CARL SKARIE,
DARIA JEROME, and GUDMUNDER HAROLDSSON

Appeal No. 2005-0150
Application No. 09/271,024

HEARD: June 7, 2005



Before WILLIAM F. SMITH, ADAMS and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 5-8 and 13-17, which are all the claims pending in the application.¹

Claims 5 and 13 are illustrative of the subject matter on appeal and are reproduced below:

5. A biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R1, R2, and R3 attached at the positions of the OH-

¹ While the examiner states (Answer, page 2), "[t]he statement of the status of the claims contained in the brief is correct," we note that appellants' Brief does not address the status of claim 12. For clarity, we note that appellants cancelled claim 12, along with claims 1-4 and 9-11 in the amendment (see page 1) received November 14, 2000.

groups of a glycerol backbone, and wherein R1, R2 and R3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R1, R2 and R3, wherein said percentages are peak area percentages as determined by gas chromatography.

13. A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R1, R2, and R3 attached at the positions of the OH-groups of a glycerol backbone, and wherein R1, R2 and R3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R1, R2 and R3, wherein said percentages are peak area percentages as determined by gas chromatography.

The references relied upon by the examiner are:

Pariza et al. (Pariza)	5,017,614	May 21, 1991
Nilsen et al. (Nilsen)	5,885,594	Mar. 23, 1999
Cain et al. (Cain)	WO 97/18320	May 22, 1997

GROUND OF REJECTION

Claims 5-8 stand rejected under 35 U.S.C. 102(a) as anticipated by Cain.

Claims 13-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cain.

Claims 5-8 and 13-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Nilsen in view of Cain and Pariza.

We reverse.

DISCUSSION

According to the examiner (Answer, page 3), the basis for each rejection is "fully set forth in prior office action, paper No. 26, mailed March 26, 2003."

However, upon inspection of the Office Action mailed March 26, 2003 (see page 2), we find that instead of providing a statement of the rejection, the examiner refers to the "reasons set forth in the prior office action." It is in the Office Action mailed August 13, 2002 where we find a statement of each rejection on this record. We remind the examiner, as set forth in § 1208(A) of the Manual of Patent Examining Procedure

Examiners may incorporate in the answer their statement of the grounds of rejection merely by reference to the final rejection (or a single other action on which it is based, MPEP § 706.07). Only those statements of grounds of rejection appearing in a single prior action may be incorporated by reference. An examiner's answer should not refer, either directly or indirectly, to more than one prior Office action. Statements of grounds of rejection appearing in actions other than the aforementioned single prior action should be quoted in the answer.

THE REJECTION UNDER 35 U.S.C. § 102:

According to the examiner (page 3, Office Action, mailed August 13, 2002),

Cain teaches [example 6] an acyglycerol composition comprising mono-[.] di-[.] and tri-glyceride[s] wherein the fatty acid[s] are c9,t11 CLA^[2] or t10, c12 CLA, wherein the total CLA in the composition is about ... [61.9%], of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer. No other CLA isomers are indicated, or suggested to be present in the composition.

² According to Cain (page 1), CLA refers to compositions containing free conjugated linoleic acid. Cf. appellants' specification (page 9), "[a]s used herein, 'conjugated linoleic acid' or 'CLA' refers to any conjugated linoleic acid or octadecadienoic free fatty acid."

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Upon review of Cain we agree with the examiner that example 6 of Cain teaches a composition comprising "61.9% of conjugated linoleic acid (CLA) of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." In addition, we agree with the examiner that Cain is silent regarding the presence of other CLA isomers that may be present in the composition. Thus, the composition taught by Cain appears, in the first instance, to meet all the limitations of appellants' claimed invention. Accordingly, we find that the examiner has established a sufficient evidentiary basis to shift the burden to appellants to demonstrate that Cain does not anticipate their claimed invention. In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) ("when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."). In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971).

In response, appellants assert (Brief, page 5), Cain "does not anticipate [c]laim[s] 5-8 because the methods utilized by Cain et al. cannot produce the claimed CLA isomer profile (i.e., a CLA composition containing less than 1%

total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid isomers)." In support of this assertion, appellants direct our attention to the Saebo Declaration, which according to appellants "establishes that the compositions of Cain et al. necessarily include the 8,10 and 11,13 isomers of CLA." According to the Saebo Declaration (paragraph 4),

In the repeat of Cain, the conjugation conditions were the same as those described in Example 6 of WO97/18320. The results of the conjugation reactions were analyzed by GC-MS. ... [T]his conjugation method resulted in a conjugated linoleic acid composition comprising approximately 3.49% c11,t13 CLA and 2.24% t9,t11 and t10,t12 CLA. The t8,c10 isomer co-elutes with the c9,t11 isomers, but almost always occurs in a one to one proportion to the c11,t13 isomer.

~~From this, appellants assert (Brief, page 8), "[a]pplicants followed the~~
exact instructions of Cain and analyzed the product. The [a]pplicants did not fail to obtain CLA. Indeed, they obtained CLA with the isomers described by Cain et al. However, the fact remains that the CLA also contained other isomers that are not mentioned by Cain." According to appellants (Brief, bridging paragraph, pages 8-9), Cain's "silence concerning the presence of the isomers cannot be equated with the absence of the isomers. ... [Cain] does not specifically define CLA to include non-active CLA isomers." On this point the Saebo Declaration states (paragraph 5),

[t]he [e]xaminer states ... that Cain teaches CLA compositions that are composed of 48.9% c9,t11 and 51.1% t10,c12 CLA, and that the analysis was carried out with gas chromatography and no other isomer of conjugated linoleic acid is detected. However, this does not mean that the other isomers were not present, as was found in my repeat of Cain. This discrepancy is explainable by the facts that 1) methods for the analysis of CLA compositions in 1996 were rather crude and 2)

Cain may have simply chosen not to include non-active isomers when reporting their results.

In addition, appellants direct our attention to Sugano³. Brief, bridging paragraph, pages 10-11.⁴ According to appellants (id.), Sugano "isomerized linoleic acid [under] conditions similar to those described by Cain...." However, as appellants explain (id.), in contrast to the results reported by Cain, Sugano's "resulting CLA preparation contained the following CLA isomers: 29.8% c9,t11/t9,c12; 1.3% c9,c11; 1.4% c10, c12; 18.6% t9,t11/t10,t12; 5.6% linoleic acid; and 13.7% other isomers." In view of the foregoing, appellants assert (Brief, page 11), "[i]n contrast to the simplified analysis presented in Cain et al., isomerization of CLA results in the production of many different isomers, not just the desired c9,t11 and t10,c12 isomers."

Appellants also direct out attention (Brief, page 11), to examples 1-4 of their specification in further support of their position that the methodology taught by Cain would have resulted in the production of CLA compositions that do not meet the limitations of their claimed invention. According to appellants (id., emphasis removed),

[t]hese examples compare non-aqueous alkali isomerization under high or low temperatures and aqueous alkali isomerization under high or low temperatures. The important fact to note is that

³ Sugano et al. (Sugano), "Conjugated Linoleic Acid Modulates Tissue Levels of Chemical Mediators and Immunoglobulins in Rats," Lipids, Vol. 33, No. 5, pp. 521-527 (1998).

⁴ Appellants also direct out attention to "Chapter 5 of the book Advances in Conjugated Linoleic Acid Research, Volume 2, J. Sebedio, W.W. Christie, and R. Adolf, Eds., AOCS Press, Champaign, IL, 2002...." See Brief, bridging sentence, pages 9-10. This reference, however, was published after appellants' March 17, 1999 filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. See In re Gunn, 537 F.2d 1123, 1128, 190 USPQ 402, 405 (CCPA 1976). Accordingly, we have not considered this reference.

each reaction, even the low temperature non-aqueous alkali isomerization reaction (Example 1, Table 6), produced a distribution of the expected isomers, not just the c9,t11 and t10,c12 isomers.

From this appellants assert (id., emphasis removed), "the compositions of Cain necessarily contained levels [of] 8,10; 11,13; and trans,trans isomers that do not meet the[ir] claimed levels."

In response, the examiner appears to back away from his original finding (page 3, Office Action, mailed August 13, 2002) that "[n]o other CLA isomers are indicated, or suggested to be present in the composition" taught by Cain. In response to appellants' arguments, and contrary to his original inference, the examiner asserts (Answer, page 4), "nowhere in Cain states that 'conjugated linoleic acid' are exclusively for c9, t11; and t10, c12 isomers." Thus, the examiner appears to concede that the CLA compositions taught by Cain would be expected to contain additional CLA isomers other than the c9, t11; and t10, c12 isomers identified by Cain.

The examiner maintains, however, "there is no convincing evidence showing that Cain's composition has the amount of the particular isomers herein claimed." Apparently the examiner is referring to the requirement of appellants' claimed invention that the acylglycerol composition comprise "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R₁, R₂ and R₃" While the examiner appreciates that the composition taught by Cain would contain CLA isomers other than t10,c12 and c9,t11 octadecadienoic acid, the examiner makes no

attempt to explain why the compositions taught by Cain would necessarily contain "less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R₁, R₂ and R₃ ..." as required by appellants' claimed invention. The only evidence on this record that addresses this point is appellants'. As discussed above, both the Saebo Declaration (using the same methodology as set forth in Cain), and the Sugano reference (using a similar methodology as set forth in Cain), resulted in a CLA composition that contained more than "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R₁, R₂ and R₃" In our opinion, the evidence of record weighs in favor of appellants, and rebuts the examiner's prima facie case of anticipation.

Accordingly, we reverse the rejection of claims 5-8 under 35 U.S.C. § 102(a) as anticipated by Cain.

THE REJECTIONS UNDER 35 U.S.C. § 103:

Cain:

According to the examiner (page 3, Office Action, mailed August 13, 2002), "Cain teaches an acylglycerol composition comprising mono-[.] di-[.] and tri-glyceride[s] wherein the fatty acids are c9,t11 CLA or t10, c12 CLA, no other CLA isomers are indicated, or suggested to be present in the composition. See, example[s] 6-10 at page[s] 16-22." The examiner finds that Cain characterize

all the fatty acid[s] through gas chromatography and ... identified the CLA. For example, in example 6, ... [Cain] state[s] "[t]he fatty

acid composition of the product, as determined by FAME GC, contained 63.8% CLA, of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." See page 16, lines 17-21.

From this the examiner asserts (id.), "the rest of the fatty acids are not CLA, and the CLA is composed entirely of cis 9, trans 11[] isomer and trans 10, cis 12 isomer."

In addition, the examiner finds (Answer, bridging paragraph, pages 3-4) that Cain teaches the use of the acylglycerol composition "in various food products including ice cream, soup, and bakery products. See, particularly, examples 12-17 at page 24-35 and the claims." The examiner recognizes, ~~however, that Cain does not teach that each of the isomers must be 30% or~~ more of the total CLA moieties for the particular food products." Answer, page 4.

Nevertheless, the examiner asserts (id.),

it would be obvious to employ such [a] CLA composition in the food product, since such [a] CLA composition [comprising 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer] has been expressly disclosed by Cain [for use in a food product]. See, ... example 6.

In response, appellants assert (Brief, page 12), "[a]s established above [with regard to the rejection under 35 U.S.C. 102(a)], the compositions of Cain necessarily contain levels [of] 8,10; 11,13; and trans,trans isomers that do not meet the claimed levels. Thus, Cain et al. does not render the claims obvious." Similarly, the examiner relies on his response to the anticipation rejection. See Answer, page 6.

Accordingly, for the reasons set forth above, we find that the evidence of record weighs in favor of appellants. Therefore, the rejection of claims 13-17 under 35 U.S.C. § 103 as being unpatentable over Cain is reversed.

Nilsen in view of Cain and Pariza:

According to the examiner (page 4, Office Action, mailed August 13, 2002), Nilsen "teach a composition comprising 90-100[]% of an acylglycerol compound wherein the fatty acid radical is a conjugated polyunsaturated fatty acid." In this regard, the examiner finds (id.), "[t]he preferred conjugated polyunsaturated fatty acid is conjugated linoleic acid which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid." The examiner recognizes, however, that Nilsen does not teach "the employment of the combination of c9, t11-octadecadienoic acid and/or t10, c12-octadecadienoic acid in the acylglycerol, or the specific amounts of each of the two isomers...."

The examiner relies on Cain to make up for Nilsen's deficiency regarding the specific c9, t11, and t10, c12 isomers of octadecadienoic acid in the acylglycerol taught by Nilsen. According to the examiner (page 5, Office Action, mailed August 13, 2002), Cain "teach[es] that both c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid are considered the active isomers of CLA, and are known to be beneficial for animal health." In this regard, the examiner relies on Pariza (id.), "to show that [a] person of ordinary skill in the art possess the skill of preparing/or isolating the pure single isomer employed herein. See,

particularly, column 4, line 50, bridging column 8, lines 68, wherein, the separation, purification, and analysis of the isomers are discussed.”

To make up for Nilsen’s failure to teach an acylglycerol composition containing at least approximately 30% c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid, the examiner asserts (id.), “[t]he optimization of the ratio of the compounds is considered within the skill of the artisan.”

Based on this evidence, the examiner finds (id.),

it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed ... invention was made, to make the composition of Nilsen et al. with acylglycerol [sic] compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid and employ the composition in feed for animals.

In this regard, the examiner asserts (id.), Nilsen did “not use ... other isomers of conjugated linoleic acids.... Therefore[, Nilsen] meet[s] the limitation set forth in claim 5 that other isomers are present in amounts less than 1%....”

In response, appellants assert (Brief, page 13), Cain “does not teach compositions comprising less than 1% 8,10; 11,13; and trans-trans isomers or methods of obtaining such compositions.” Regarding Nilsen, appellants assert (id., emphasis removed), like Cain, Nilsen “provides no such compositions or methods [nor does Nilsen] teach any method at all for conjugation, they merely list CLA in a long list of fatty acids that may be useful in their invention.” In support of this assertion, appellants rely on paragraph 6 of the Saebo Declaration which states “[w]ith respect to the Nilsen reference, I note that it does not provide any method of producing conjugated linoleic acid having less

than 1% 8,10; 11,13; and trans-trans isomers." Regarding Pariza, appellants assert (Brief, bridging paragraph, pages 13-14), "does not teach preparation of CLA in amounts suitable for incorporation into acylglycerides. Indeed, the HPLC purified isomers are produced for use as chromatography standards. Importantly, because the isomers are produced for use as standards, Pariza does not teach or suggest combining the isomers to form a composition containing both t10,c12 and t9,c11 isomers are required by the [c]laims." See also Saebo Declaration, paragraph 7. Accordingly, appellants assert (Brief, page 14), Pariza "teaches away from a combination of isomers as required by the [c]laims."

In response, the examiner addresses each reference individually. Accordingly, we will address the examiner's discussion of each reference in turn.

Cain:

The examiner relies (Answer, page 8) on his response to the anticipation rejection to address appellants' assertions regarding Cain. Accordingly, for the reasons set forth above, we are not persuaded by the examiner's assertion.

Nilsen:

Regarding Nilsen, the examiner asserts (id.), "one of ordinary skill in the art would have been expected to be able to practice the invention claimed by Nielsen [sic], including making an acylglycerol compound wherein the Rs are conjugated linoleic acids (specifically defined as c9, t11; t10, c12 isomers), see the claims in Nielsen [sic] et al." We fail to see the relevance of the examiner's reference to the claims of Nilsen. Upon consideration of Nilsen's claimed

invention we find no specific reference to c9, t11; t10, c12 isomers of CLA. At best, Nilsen's claims relate to a genus of CLA isomers. In this regard, we note the examiner's reference (Answer, page 6, emphasis added), to column 4, lines 4-6 of Nilsen, for what the examiner believes to be Nilsen's disclosure of "[t]he preferred conjugated polyunsaturated fatty acid ... which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid." Appellants' claimed invention is directed to, inter alia, an acylglycerol composition containing at least approximately 30% t10, c12 octadecadienoic acid, not c10, t12-octadecadienoic acid. The examiner identifies no section of Nilsen, and we find none, that would suggest appellants' specific acylglycerol composition. Further, the examiner offers to response to appellants' assertion that Nilsen provides no method through which to produce an acylglycerol composition as set forth in appellants' claimed invention. Accordingly, we are not persuaded by the examiner's assertions to the contrary.

Pariza:

In response to appellants' argument concerning Pariza, the examiner asserts (Answer, page 8), "[a]ppellants concede[] that Paris [sic] et al. does provide purified CLA isomers, but nevertheless argue that Pariza's disclosure is for producing standard samples for HPLC, and is not in a scale suitable for making acylglycerol herein claimed." To this the examiner asserts (id.), "there is no limitation as to the quantity of the composition in claims 5-8." On reflection, we are not persuaded by the examiner's assertions.

While appellants do not dispute that Pariza teaches methods of making t10, c12 and c9, t11 octadecadienoic acid, appellants assert (Brief, page 13), "Pariza does not teach preparation of CLA in amounts suitable for incorporation into acylglycerides. Indeed, the HPLC purified isomers are produced for use as chromatography standards." In response, the examiner does not dispute that amount of t10, c12 and c9, t11 octadecadienoic acid produced in the method of Pariza would not be sufficient to produce appellants' claimed acylglycerol composition. Instead, the examiner concludes (Answer, page 8), "preparative HPLC would be obvious to one of ordinary skill in the art with similar condition[s]." Apparently, it is the examiner's position that a person of ordinary skill in the art would have found it obvious to scale-up the method taught by Pariza to produce a sufficient amount of t10, c12 and c9, t11 octadecadienoic acid to incorporate into acylglycerol molecules. The evidence of record, however, does not support the examiner's assertion. Further, the examiner fails to provide any evidence that the method taught by Pariza could be effectively scaled-up to produce the acylglycerol molecules required by appellants' claimed invention. In the absence of a reasonable expectation of success one is left with only an "obvious to try" situation which is not the standard of obviousness under 35 U.S.C. § 103. See In re O'Farrell, 858 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

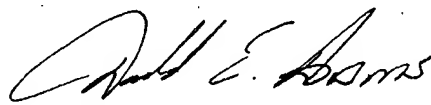
In order to establish a prima facie case of obviousness, there must be more than the demonstrated existence of all of the components of the claimed subject matter. There must be some reason, suggestion, or motivation found in

the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge cannot come from the applicants' disclosure of the invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). On the record before us, we find no reasonable suggestion for combining the teachings of the references relied upon by the examiner in a manner which would have reasonably led one of ordinary skill in this art to arrive at the claimed invention. The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In our opinion, the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness.

Accordingly, we reverse the rejection of claims 5-8 and 13-17 under 35 U.S.C. § 103 as being unpatentable over Nilsen in view of Cain and Pariza.

REVERSED


William F. Smith
Administrative Patent Judge


Donald E. Adams
Administrative Patent Judge


Eric Grimes
Administrative Patent Judge

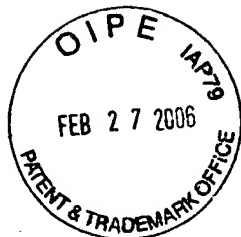
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The opinion in support of the decision being entered today is not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

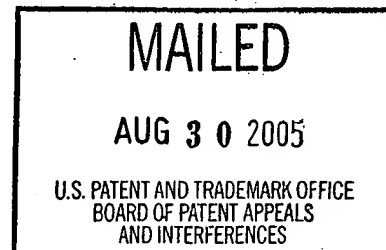
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



Ex parte ASGEIR SAEBO, and CARL SKARIE

Appeal No. 2005-1578
Application No. 09/132,593

ON BRIEF



Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-6 and 8, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A food product comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers.

The references relied upon by the examiner are:

Baltes et al. (Baltes)

3,162,658

Dec. 22, 1964

Cook et al. (Cook) 5,554,646 Sep. 10, 1996

Cain et al. (Cain) WO 97/18320 May 22, 1997

Chin et al. (Chin), "Dietary Sources of Conjugated Dienoic Isomers of Linoleic Acid, a Newly Recognized Class of Anticarcinogens," J. Food Composition And Analysis, Vol. 5, pp. 185-197 (1992)

GROUND OF REJECTION

Claims 1-6 and 8 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Cook, Cain, Chin and Baltes.

We reverse.

DISCUSSION

According to the examiner (Answer, page 3), Cook "teach an active form of conjugated linoleic acid, i.e., 10,12-octadecadienoic acid and 9,11-octadecadienoic acid, which includes esters, salts and free acids of conjugated linoleic acid." In addition, the examiner finds (Answer, page 4), Cook teach that "[t]he conjugated linoleic acid may be obtained through isomerization of safflower oil;" "a food product comprising said active form of conjugated linoleic acid;" and that "[c]9, t11- and t10, c12-isomer[s] are the predominantly major isomers of the conjugated linoleic acid active form...." According to the examiner Cook do not teach 8,10- and 11,13-octadecadienoic acid isomers. Id. Therefore, the examiner reasons (id.), since Cook does not mention the 8,10- and 11,13-octadecadienoic acid isomers they must not be present and therefore, Cook meets appellants' claimed requirement of less than 2 percent 8,10- and 11,13-octadecadienoic acid isomers.

Regarding Chin and Cain, the examiner finds (id.), Chin "teach that it is known that c9;t11-conjugated linoleic acid isomer is an active form of conjugated linoleic acid," and that Cain "teaches a CLA [(conjugated linoleic acid)] composition made from sunflower oil for food additive contains 48.9% of c9, t11, 51.1% of t10,c12 linoleic acid or their esters."

Based on this evidence the examiner concludes (Answer, page 5),

it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed ... invention was made, to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9, t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 1,13-octadecadienoic ester, such as those disclosed by Cain et al., and employ the mixture in food products.

In response, appellants argue (Brief, page 6), the Sæbo Declaration establishes that the compositions of Cook and Cain "cannot produce alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers." According to the Sæbo Declaration (received December 9, 2004), repeat experiments were performed using the methodology described in Cook and Cain. For Cook, the Sæbo Declaration reports (paragraph 4),

this conjugation method resulted in in [sic] a conjugated linoleic acid composition comprising approximately 1.58% c11,t13 CLA and 2.34% t9,t11 and t10,t12 CLA. The t8,c10 isomer co-elutes with the c9,t11 isomers, but almost always occurs in a one to one proportion to the c11,t13 isomer.

Accordingly, the trans,trans isomers resulting from Cook's conjugation method are outside the requirements of appellants' claimed invention, which requires, inter alia, less than two percent trans, trans isomers.

Regarding Cain, the Sæbo Declaration reports (paragraph 6)

this conjugation method resulted in a conjugated linoleic acid composition comprising approximately 3.49% c11,t13 CLA and 2.24% t9,t11 and t10,t12 CLA. The t8,c10 isomer co-elutes with the c9,t11 isomers, but almost always occurs in a one to one proportion to the c11,t13 isomer.

Accordingly, the trans,trans isomers resulting from Cain's conjugation method are outside the requirements of appellants' claimed invention, which requires, inter alia, less than two percent trans, trans isomers.

In response, the examiner asserts (Answer, page 6), "the declaration fails to establish the fact that the conjugated linoleic acid disclosed by Cook or Cain as recited in the prior office action contains more than 2% of the isomers identified in claim 1 herein." In support of this assertion, the examiner finds (Answer, bridging paragraph, pages 6-7), while Cain acknowledges the existence of trans,trans isomers, Cain "do not disclose the presence of trans isomers in their CLA composition." Apparently, the examiner is of the opinion that since Cain and Cook do not specifically state that their CLA compositions contain isomers other than t10,c12- and c9,t11-octadecadienoic acid, the CLA compositions taught by Cain and Cook only contain t10,c12- and c9,t11-octadecadienoic acid. We are not persuaded by the examiner's assertion.

According to Cook (column 1, lines 65 to column 2, line 3);

[I]n one preferred embodiment of the method of the present invention the safe and effective amount of conjugated linoleic acid, which is selected from 9,11-octadecadienoic acid; 10,12-octadecadienoic acid; mixtures thereof; and non-toxic salts thereof is added to the feed of an animal in which it is desired to reduce the body fat.

We note, however, that according to Cook (column 4, lines 22-24, emphasis added), "[t]he terms 'conjugated linoleic acids' and 'CLA' as used herein are intended to include 9,11-octadecadienoic acid, [and] 10,12-octadecadienoic acid...." Thus, while Cook emphasizes the 9,11- and 10,12-octadecadienoic acid isomers, Cook leaves his definition of CLA open to "include" other isomers. ~~In addition, Cook does not distinguish which geometric isomer is intended by the~~ recitation of 9,11-octadecadienoic acid and 10,12-octadecadienoic acid. In this regard, we note that there is no requirement in Cook's claims that a particular CLA, let alone a particular geometric isomer of 9,11- or 10,12-octadecadienoic acid is required. Further, while the examiner recognizes (Answer, page 4), Cook discloses that "[c]9,t11- and t10,c12-isomer[s] are the predominantly major isomers of the conjugated linoleic acid...", the examiner fails to appreciate that Cook discloses (column 4, lines 48-50), "8 possible geometric isomers of 9,11 and 10,12-octadecadienoic acid (c9,c11; c9,t11; t9,c11; t9,t11; c10,c12; c10,t12; t10,c12 and t10,t12)...", all of which fall within Cook's definition of CLA. Accordingly, we fail to understand how the examiner has read Cook's disclosure as limited to a composition containing only the c9,t11- and t10,c12-isomers of octadecadienoic acid.

According to Cook (column 4, lines 28-29), "[t]he preferred method of synthesizing CLA is that described in Example 1", which appears in Column 2 of Cook. According to the Sæbo Declaration, in the repeat of Cook, "the conjugation conditions were the same as those described in [c]olumn 2 of ... [Cook]." The results reported in the Sæbo Declaration are consistent with Cook in that a CLA composition was obtained that included the 9,11 and 10,12 isomers of octadecadienoic acid. Cf. Cook, column 4, lines 22-24, emphasis added), "[t]he terms 'conjugated linoleic acids' and 'CLA' as used herein are intended to include 9,11-octadecadienoic acid, [and] 10,12-octadecadienoic acid...." While the results reported in the Sæbo Declaration are consistent with the disclosure of Cook, they are inconsistent with the requirements of appellants' claimed invention, because they include more than 2% of the trans,trans octadecadienoic acid isomer. Specifically, the resulting CLA composition contains, inter alia, 2.34% t9,t11 and t10,t12 CLA. For the foregoing reasons we are not persuaded by the examiner's assertions regarding Cook.

Regarding Cain, the reference discloses (page 3), "our invention concerns a new process for the preparation of CLA's, wherein the ratio $\frac{\text{cis}^9\text{-trans}^{11}}{\text{trans}^{10}\text{-cis}^{12}}$ can be chosen freely." Therefore, contrary to the examiner's assertion (Answer, page 7), it is not unreasonable for Cain to not report on the presence of other isomers in his CLA compositions, isomers other than cis⁹-trans¹¹ and trans¹⁰-cis¹² were simply not the focus of his invention. Cf. Sæbo Declaration, paragraph 7, "Cain may have simply chosen not to include non-

active isomers when reporting their results.” In this regard, we note that Cain state (page 5), “our invention also concerns novel organic materials, ... wherein the conjugated polyunsaturated fatty acid moieties at least comprise two isomers L₁ and L₂” According to Cain (id.), “is it preferred that L₁ and L₂ are cis⁹ trans¹¹ and trans¹⁰ cis¹²-linoleic acid (or vice versa)[.]” See also, for example, claims 1, 6 and 9 of Cain, wherein similar language is used.

Therefore, similar to the facts in Cook, while Cain emphasizes the cis⁹ trans¹¹ and trans¹⁰ cis¹² isomers, Cain’s compositions may comprise other CLA isomers. Accordingly, we see nothing inconsistent with the results of the repeat of Cain’s methodology as presented in the Sæbo Declaration. Paragraph 6 of the Sæbo Declaration, and the results attached at Tab 2 of the Declaration, reports that Cains’ methodology results in a composition comprising at least two isomers, the cis⁹ trans¹¹ and trans¹⁰ cis¹² isomers. The results also demonstrate however, that other isomers are also present in the resulting composition. Specifically, the resulting CLA composition contains, inter alia, 2.24% t9,t11 and t10,t12 CLA. For the foregoing reasons we are not persuaded by the examiner’s assertions regarding Cain..

On reflection, we disagree with the examiner’s conclusion (Answer, page 5), that it would have been prima facie obvious to a person of ordinary skill in the art, at the time the invention was made to combine the teachings of Cain, Cook and Chin¹ in the manner necessary to arrive at appellants’ claimed invention.

¹ In our opinion, the examiner’s reliance (Answer, page 4) on Chin to teach that c9,t11-conjugated linoleic acid isomer is an active form of conjugated linoleic acid, is insufficient to make up for the deficiency in the combination of Cain and Cook.

We also note the examiner's reliance on Baltes (Answer, page 5), to "teach that employment of low alkali alcoholate as catalysts for isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers is known." However, in our opinion, Baltes fails to make up for the deficiency in the combination of Cain and Cook.

Prima facie obviousness based on a combination of references requires that the prior art provide "a reason, suggestion, or motivation to lead an inventor to combine those references." Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

[E]vidence of a suggestion, teaching, or motivation to combine may ~~flow from the prior art references themselves, the knowledge of one~~ of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. . . . The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.

In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted). The suggestion to combine prior art references must come from the cited references, not from the application's disclosure. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Based on the foregoing, it is our opinion that the examiner failed to meet his burden of presenting the evidence necessary to support a prima facie case of obviousness. If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Accordingly, we reverse the rejection of claims 1-6 and 8 under 35 U.S.C.
§ 103 as being unpatentable over the combination of Cook, Cain, Chin and
Baltes.

REVERSED


William F. Smith
Administrative Patent Judge


Donald E. Adams
Administrative Patent Judge


Eric Grimes
Administrative Patent Judge

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Appeal No. 2005-1578
Application No. 09/132,593

Page 10

MEDLEN & CARROLL, LLP
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Sæbo *et al.*

Serial No.: 09/544,084

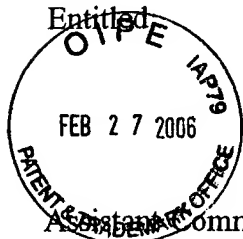
Group No.: 1617

Filed: 04/06/00

Examiner: Wang

Entitled:

CONJUGATED LINOLEIC ACID COMPOSITIONS



Declaration of Asgeir Sæbo

Asgeir Sæbo, Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated:

10-15-01

By:

Mary Ellen W. Wang

I, Dr. Asgeir Sæbo, state as follows:

1. My present position is Director of Research, Natural AS.
2. I have reviewed the above captioned patent application, of which I am an inventor, the Office Action mailed July 23, 2001, and the Cook, Baltes, and Lievense patents cited as prior art.
3. After review of the cited references, I conclude that the references do not teach methods of producing conjugated linoleic acid suitable for oral consumption with alcoholate catalysts. In fact, only one of the cited references, Baltes, teaches the use of alcoholate catalysts for any purpose. It is my understanding that in the Office Action the Examiner states that "[t]he citation of Baltes et al. (U.S. Patent 3,162,658) is to show the level of ordinary skill in the art."
4. Contrary to the Examiner's opinion, the Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and conjugated linolenic

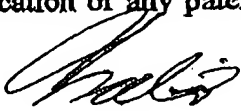
acid (CLnA) for technical purposes such as drying oils and paint varnishes. In particular, Column 1, line 30 of the Baltes patent provides that "[t]he latter ones, namely the unconjugated polyethenoid acids occur in nature in large quantities, while conjugated polyethenoid acids are relatively seldom found in fats and oils of natural origin except for woods oils such as tung oil. The latter compound and also its derivatives are of great technical interest and therefore, many attempts were made to isomerize unconjugated polyethenoid acids to conjugated acids." The Baltes patent is solving the problem of providing substitute conjugated acids for naturally occurring conjugated acid sources such as tung oil. Therefore, the methods of the Baltes patent are intended to produce an oil suitable for the same purposes as tung oil. Tung oil is not edible and the tung tree is listed in the "Poisonous Plant Bibliography" of the United States Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Plant and Dairy Food and Beverages. The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in many ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manners." Based on the disclosure of the Baltes, Cook and Lievense patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.

5. Other disclosure in the Baltes patent also indicates the unsuitability of the methods for the production of edible CLA. Conjugated acids are inherently unstable. Stability is related to the number of double bonds. The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunsaturated fatty acids. These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts of breakdown products and unwanted polymers, especially when conjugated. However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

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PATENTAttorney Docket No. **CONLINCO-04286**

6. I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Dr. Asgeir Sæbo

Date: Oct 12 2001